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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/734,876 | 12/12/2003 | Howard T. Bellin | 2003-2090.CON | 1026 |
| 23165 | 7590 | 04/08/2005 | EXAMINER | |
| ROBERT J JACOBSON PA 650 BRIMHALL STREET SOUTH ST PAUL, MN 551161511 | | | SNOW, BRUCE EDWARD | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3738 | |

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

9P

Office Action Summary

Application No.

10/734,876

Applicant(s)

BELLIN ET AL.

Examiner

Bruce E Snow

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,23,26,28-33 and 35-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,23,26,28-33 and 35-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/19/05
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's amendment filed January 19, 2005 has been fully considered. The double patenting rejection has been withdrawn in view of the terminal disclaimer submitted February 23, 2005.

Applicant's amendments and arguments regarding the McGahn et al rejection are not persuasive. Applicant argues that the implant of McGahn et al is not "one-piece" and is constructed from five separate pieces. It is the Examiner's position that the separate pieces cemented together form a final product that is "one-piece". The Examiner cannot differentiate between McGahn et al using separate silicone elastomer elements cement together with a silicone elastomer forming one-piece and applicant using a four layer envelope that is cured together forming one-piece.

Additionally, applicant has added the language wherein the envelope is sealable after being filled with said fluid which is merely functional language. The implant of McGahn et al is fully capable of being sealed by a patch after being filled, etc.; note that the implant has a valve 15 which does seal after being filled.

Regarding the rejection in view of Baker, the Examiner logic is the same as that used for McGahn et al. It is the Examiner position that elements that are glued/cement or cured together both form a one-piece implant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 23, 26, 28-33, 35-46 (all claims) are rejected under 35 U.S.C. 102(b) as being anticipated by McGhan et al (3,852,832).

McGhan et al teaches a breast implant comprising a fillable "envelope" having one side having a relatively smooth surface and another side (comprising 12a, 12d, and 37) having a relatively rough surface to allow for tissue ingrowth. The implant, as clearly shown in figures 3-4, has a relatively thicker side comprising said relatively rough surface.

Note column 2, lines 53 et seq., teaching the implant is formed to a mold and then stripped leaving an aperture opening which is later closed by a closer 12d, interpreted as a patch.

Regarding claims 42-46, McGhan et al teaches the thickness of sheet 37 which is the only thickness over the aperture 12c, and is approximately 20/1000 inches thick

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which is interpreted as being about 18/1000 inches thick. From the drawings, the smooth surface is shown as being thinner and is interpreted as being within the claimed range.

Claims 21, 23, 26, 28-33, 35-46 (all claims) are rejected under 35 U.S.C. 102(b) as being anticipated by Prescott (5,522,896).

Referring to figure 1B, Prescott teaches a breast implant comprising a fillable "envelope" having a relatively smooth anterior surface and a thicker posterior side comprising elements 4 and 6. Prescott teaches an additionally layer/coating 4 on a breast prosthesis:

"The prosthesis of the present invention can also comprise a base material of predetermined shape, e.g., a conventional prosthetic device, and a layer of elastomeric material provided on the base material, wherein the layer of elastomeric material has distributed therein or provided thereon bio-active ceramic or glass particles (column 5, lines 34-39)."

Inherently, a conventional prosthetic with an additionally coating, such as the breast implant such in figure 1B, would produce a thicker posterior side relative to the anterior side. It is noted that Prescott teaches the coating to increase tissue adhesion; see at least column 1, lines 29-38. The posterior surface with coating is relatively rough when compared with the anterior surface without a coating. The implant is fully capable of being sealable after being filled.

Claims 28, 30, 32, 39, 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Baker (5,026,394).

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Baker teaches a breast implant comprising a fillable "envelope" having a relatively smooth anterior surface and a thicker posterior side 20, 14. Said implant envelope is sealed, and wherein the envelope apart from said patch 34, 72 is one piece.

Note column 6, lines 65-66, "the shell component and the reinforcement member can be formed as an integral unit."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

In the alternative, claims 42-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGhan et al (3,852,832) or Precott (5,522,896).

McGhan et al discloses the invention as described above including the thickness as described above. Lacking any criticality in the specification, the use of the claimed thicknesses lacks criticality in the specification and solves no stated problem and would have been an obvious matter of design choice within the skill of the art. Additionally, it would have been obvious to one having ordinary skill in the to adjusted the thickness of both sides of the implant to adjust flexibility and/or increase strength.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRUCE SNOW
PRIMARY EXAMINER